TECHNICAL SERVICES MONTHLY REPORT

LABS CLUSTER

Dec 2022 and Jan 2023

TSD Approach

Service Capabilities

- On time deliverables
- Quality Work

Trouble shooting

- Unit Process
- Unit operations

Cont. Improvement

- Solvent Yield
- Capacity

Ongoing Projects

LABS 1	LABS 2	LABS 3	PHARMA CHEM
• Solvent-8 • Quality-1 • Capacity – 1	• Solvent-1 • Yield -1 • Capacity-1	• Capacity-1	• Solvent-5 • Yield -2 • Capacity-2

LABS - I

1) **Solvent Reduction at Source**

2) **Solvent Loss Minimization**

3) **Capacity**

4) **Quality Trouble shooting**

5) **New Proposal**

Solvent Reduction at Source

Product Name: Duloxetine Hydrochloride

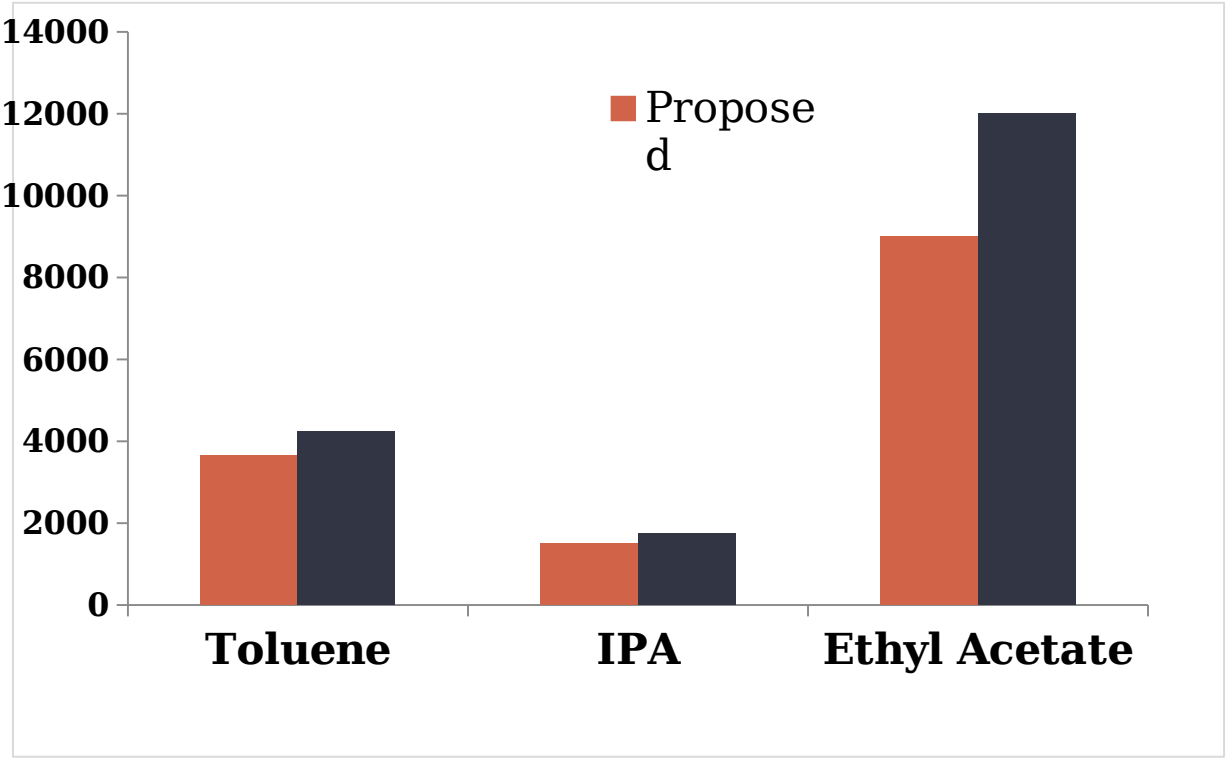
Stage Code : DLR2

Block: P

Quality complies

% Yield 75 % against 89%

Solvent Name	Quantity in L	
	Existing	Proposed
Toluene	4250	3650
IPA	1750	1500
Ethyl Acetate	12000	9000



Solvent Reduction at Source

Product Name:
Olmesartan Medoxomil

Stage Code : OMX2

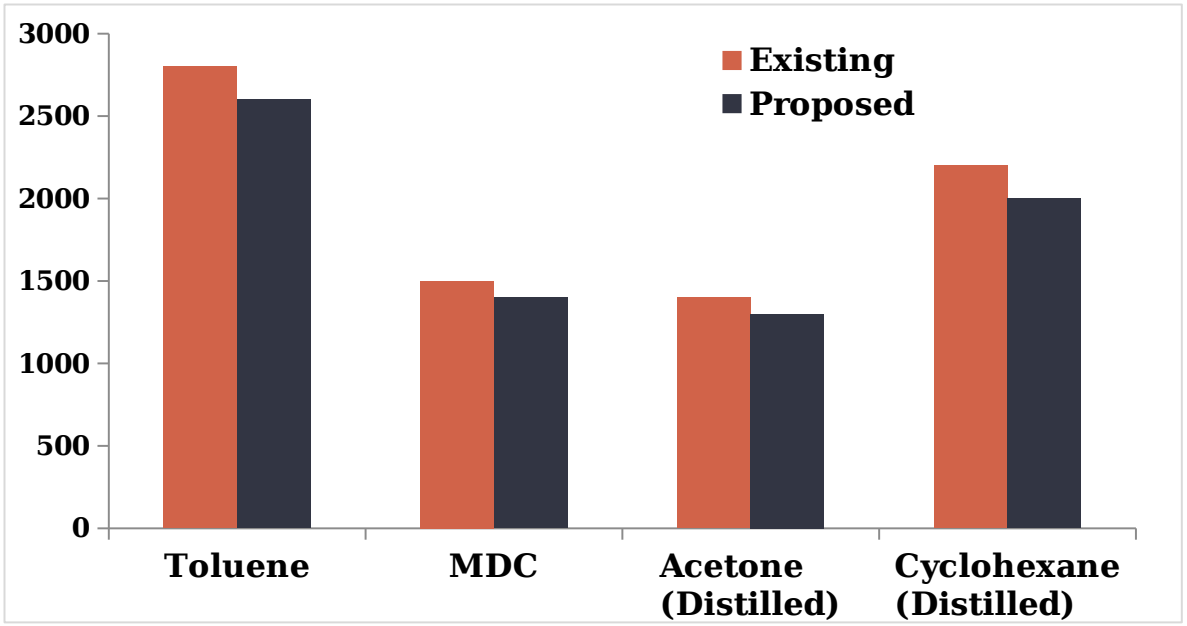
Block: R

Batch Input: 400 Kg.

Batch Output: Results Awaited

% Yield :

Solvent Name	Quantity, Lt.	
	Existing	Proposed
Toluene	2800	2600
MDC	1500	1400
Acetone (Distilled)	1400	1300
Cyclohexane (Distilled)	2200	2000



Solvent – Loss Minimization

Product Name : Pantaprazole Sodium

Stage : PTP1

Block : P & H

Batch Input : 180 Kg.

Solvent Name : MDC

Solvent Input : 2300 Lt.

On Distillation below 20°C at 300 mm Hg Vacuum for

Block / Status	P Block	H Block
Past Output, Lt.	600	400
Present Output, Lt.	1000	950

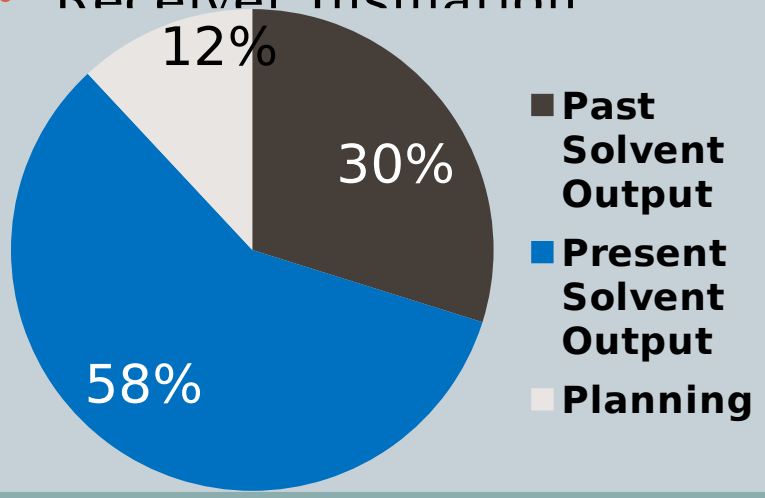
Conclusion:

Improvements Methods:

- Brine Cooling to Condenser

Upcoming Improvements:

- AOD pump
- Receiver Insulation



Solvent – Loss Minimization

Product Name :Duloxetine Hydrochloride

Stage : DUC1

Block : P

Batch Input : 250 Kg.

Solvent Name : MTBE

Solvent Input : 3500 Lt.

On Distillation below 30°C at 550-600mm Hg Vacuum for Approx. 50hr.

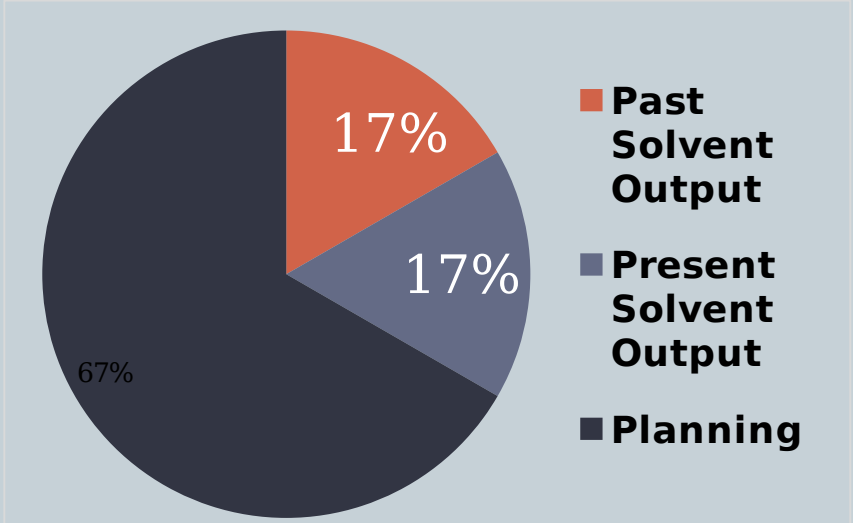
Past Solvent Output : 750 Lt.

Planning Output : 3000 Lt.

Conclusion:

Proposal for Upcoming Improvements:

- Brine Cooling to Condenser
- Receiver Insulation



Further Solvent – Loss Minimization

Product Name :Duloxetine Hydrochloride

Stage : DUC1

Block : P

Batch Input : 250 Kg.

Solvent Name : MTBE

Solvent Input : 3500 Lt.

On Distillation below 30°C at 550-600mm Hg Vacuum for Approx. 50hr.

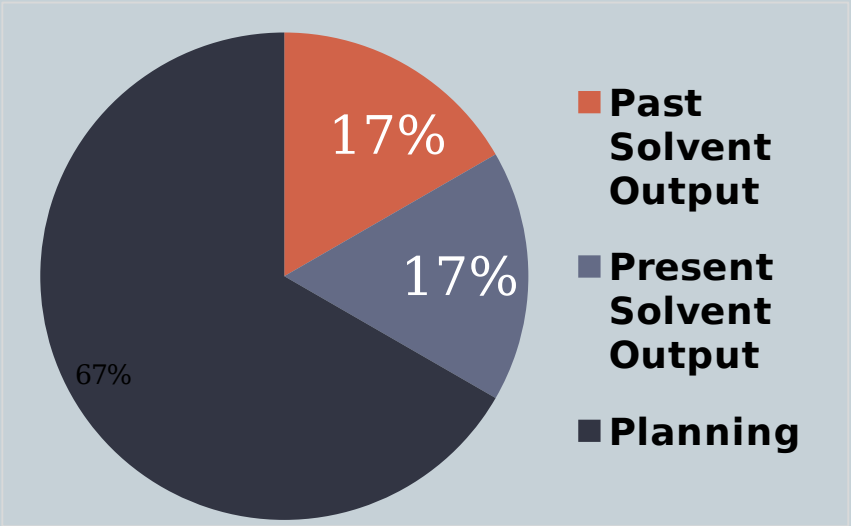
Past Solvent Output : 750 Lt.

Planning Output : 3000 Lt.

Conclusion:

Proposal for Upcoming Improvements:

- **Brine Cooling to Condenser**
- **Receiver Insulation**



LABS-1 :
Solvent – Diverted from Job Work

- Spent Solvent Diverted to Job Work –

  - **November Month Savings – 7.8 Lakhs**
  - **December Month Savings – 7.8 Lakhs**
  - **January Month Savings – 3.7 Lakhs**

Nov -22 Cost saving sheet

Dec -2022 Cost saving sheet

Microsoft Excel Worksheet

Jan 2023 Cost saving sheet

oxit Reader PDF Document

Quality (Rosuvastatin Calcium)

Product: Rosuvatsatin API Higher Scale of 125 kg input

Concern: XRD not complies for M/s Torrent Pharma, as lower scale complies.

Approach and Evaluation: Conducted various experiments at Polymorph lab identified filtration delay could be probable root cause.
Compared geometric similarity, kinematic similarity and dynamic similarity of lower and higher scale.

Conclusion: mixing profile and occupancy to be matched. RPM

New Proposal : Centrifuge is bottleneck- new design has been proposed . Proof of concept will be planned by march 2023.

Quality Improvements

Product: Dabigatran API

Concern: PSD D 90 < 7 micron and GTI NMT 0.002 PPM

Approach and Evaluation: Conducted various experiments at pharma stage in plant R&D.

Wayforward: **Control Nitrite from tech stage**

New proposal : N-1 and Pharma

1. Use advanced carbon free from nitrites during purification of free base
2. Use 0.2 absolute PTFE filter for Mass + Acetone and 0.2 absolute for MSA + Acetone

Multi stage Homogenizer with to reduce particle size during crystallization

Capacity Enhancement

Product: Aliskerene from 1.8 TPA to 6.0 TPA

Proposal : New Z block with 16 stages , Pharma satge in M Block

- Technical Evaluation – Completed .
- Utility Load. U/P
- Solvent Recovery and reuse proposal U/P
- Effluent Handling U/P

New Proposal

- Trail planned for various unit operations in Pilot Model
- Centrifugal Extractor for Solvent Extraction and Quantity Optimization
- Falling Film Evaporator and ATFE to reduce distillation Cycle time reduction
- Homogenizer for particle Size reduction

PHARMACHEM